

# Hundreds of French Citizens Suffer Cardiac Events After Bivalent Boosters

30 Day Regulatory Window Captures Heart Attacks, Strokes, and Blood Clots

By Dr. Peter McCullough

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Theme: <u>Science and Medicine</u>

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I have served on or chaired two dozen data safety monitoring boards for randomized trials of novel experimental drugs or devices. I can tell you first hand that for COVID-19 vaccines, a 30 day regulatory window after injection is fair game for attribution of health events to the product when the adverse events of interest are known to be caused by the mRNA induced Wuhan Spike protein.

Jabagi et al, NEJM, reported from the French National Health Data System linked to the national COVID-19 vaccination database disclosing cardiovascular events after mRNA BA4/BA5 bivalent boosters. All persons who were 50 years of age or older and who had received a booster dose between October 6 and November 9, 2022, were included in the study. The composite of ischemic/hemorrhagic stroke, myocardial infarction, or pulmonary occurred in 335 unfortunate individuals. The authors make the mistake of dividing by the cases by the entire number vaccinated and comparing rates to monovalent boosters. Neither of these operations are valid since there is incomplete capture of events and comparison was not made to a placebo or control group.

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# Stroke, Myocardial Infarction, and Pulmonary Embolism after Bivalent Booster

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Table 1. Comparison between the Events.*	Bivalent Booster and the Orig	inal Monovalent Booster in th	e Risk of Cardiovascular
Cardiovascular Event	Bivalent Vaccine (N = 373,728)	Monovalent Vaccine (N = 97,234)	Hazard Ratio (95% CI)†
	no. of events (%)		
Ischemic stroke	114 (0.030)	34 (0.035)	0.86 (0.58-1.27)
Hemorrhagic stroke	43 (0.011)	14 (0.014)	0.86 (0.46-1.61)
Myocardial infarction	117 (0.031)	34 (0.035)	0.92 (0.62-1.36)
Pulmonary embolism	62 (0.017)	22 (0.023)	0.83 (0.49-1.40)
All four events combined	335 (0.090);	104 (0.107)	0.87 (0.69–1.09)

<sup>\*</sup> Listed are four categories of cardiovascular events that were recorded in the French National Health Data System and that occurred within 21 days after the receipt of either the Pfizer–BioNTech bivalent mRNA vaccine targeting both the ancestral and omicron BA.4–BA.5 sublineages of SARS-CoV-2 or the original monovalent vaccine. All the participants received their booster injection between October 6 and November 9, 2022.

Jabagi MJ, Bertrand M, Botton J, Le Vu S, Weill A, Dray-Spira R, Zureik M. Stroke, Myocardial Infarction, and Pulmonary Embolism after Bivalent Booster. N Engl J Med. 2023 Mar 29. doi: 10.1056/NEJMc2302134. Epub ahead of print. PMID: 36988584.

These data suggest that large numbers of well-characterized, serious, and potentially fatal safety events are occurring within 21 days after bivalent mRNA boosters.

All of these events should be considered to be serious and directly attributable to COVID-19 vaccination, and conversely, if the injections were not received, these individuals in all probability would be alive and free of these complications today.

\*

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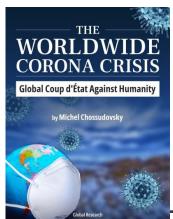
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Featured image: A hand holding an mRNA vaccine vial. (Spencer Davis / Unsplash)

<sup>†</sup> Hazard ratios for the risk in the bivalent vaccine group were estimated with the use of propensity score—weighted Cox models. Details are provided in the Supplementary Appendix.

<sup>‡</sup> One of the participants who received a bivalent vaccine had two cardiovascular events, so his data were censored after the first event for a total number of 335 events.



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